NICE National Institute for Health and Care Excellence

NICE Pathways

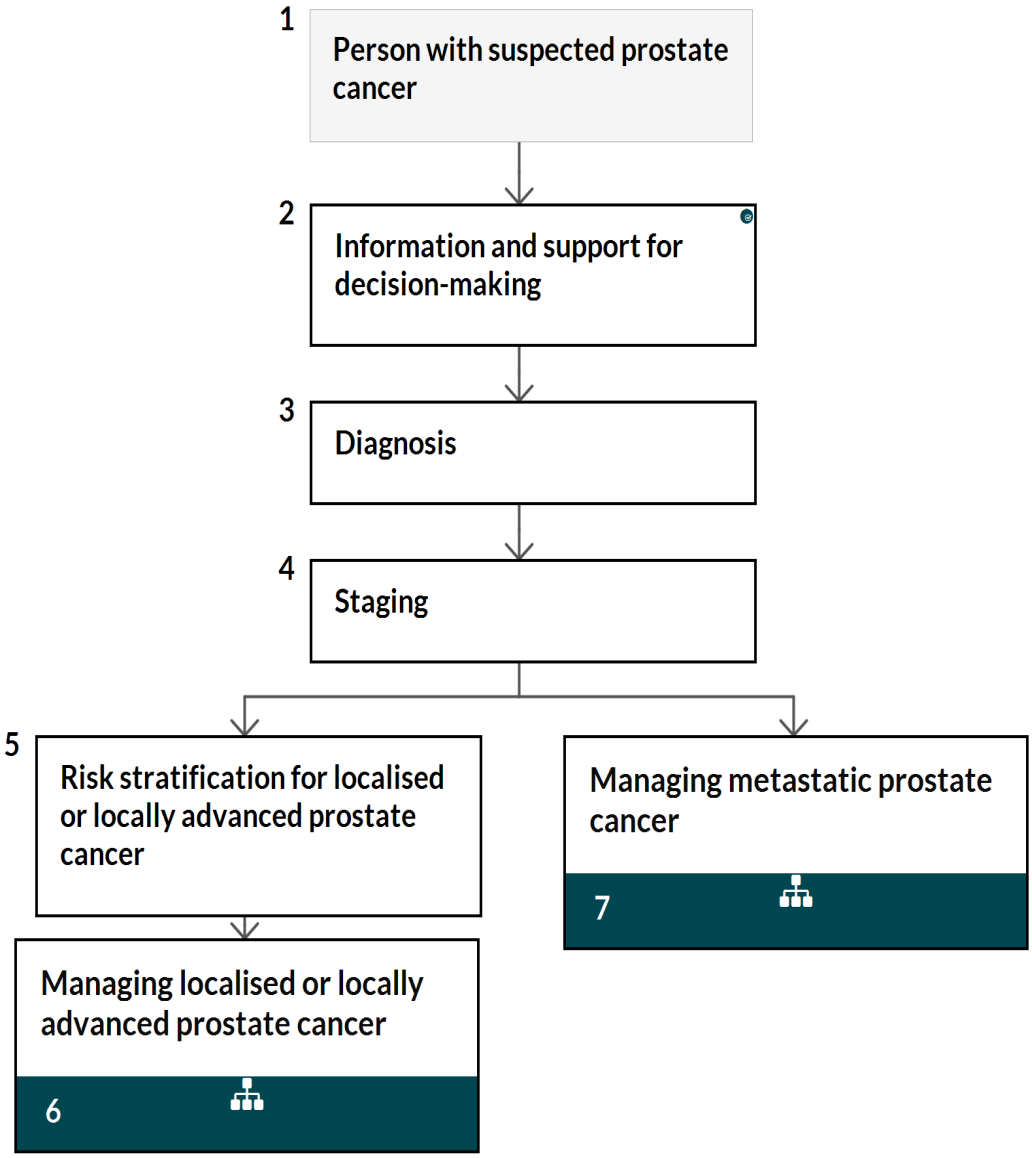
Assessing suspected prostate cancer

NICE Pathways bring together everything NICE says on a topic in an interactive flowchart. NICE Pathways are interactive and designed to be used online.

They are updated regularly as new NICE guidance is published. To view the latest version of this NICE Pathway see:

http://pathways.nice.org.uk/pathways/prostate-cancer
NICE Pathway last updated: 30 December 2021

This document contains a single flowchart and uses numbering to link the boxes to the associated recommendations.



1 Person with suspected prostate cancer

No additional information

2 Information and support for decision-making

Information

For advice on communication and patient-centred care throughout the patient journey, follow the recommendations in the NICE cancer service guidelines on improving outcomes in urological cancers and improving supportive and palliative care for adults with cancer.

Offer people with prostate cancer information tailored to their own needs. This information should be given by a healthcare professional (for example, a consultant or specialist nurse) and may be supported by written and visual media.

Offer people with prostate cancer advice on how to get information and support from websites, local and national cancer information services, and from cancer support groups.

Choose or recommend information resources for people with prostate cancer that are clear, reliable and up to date. Ask for feedback from people with prostate cancer and their carers to identify the highest quality information resources.

NICE has written information for the public on prostate cancer.

Support for decision-making

Find out the extent to which the person wishes to be involved in their decision making, and ensure that they have sufficient information to do so.

Use an up-to-date decision aid in all urological cancer MDTs. Healthcare professionals trained in its use should offer it to people with localised prostate cancer when making treatment decisions.

Use nomograms together with people with prostate cancer to help:

- with decision making
- predict biopsy results
- predict pathological stage

- predict risk of treatment failure.

Explain the reliability, validity and limitations of any predictions made using nomograms.

Discuss all relevant management options in this guideline with people with prostate cancer and their partners or carers, even if they are not available through their local services.

Tell people with prostate cancer:

- about treatment options and their risks and benefits in an objective, unbiased manner **and**
- that there is limited evidence for some treatment options.

Ensure that mechanisms are in place so people with prostate cancer and their primary care providers have access to specialist services throughout the course of their disease.

Tell people with prostate cancer and their partners or carers about the effects of prostate cancer and the treatment options on their:

- sexual function
- physical appearance
- continence
- other aspects of masculinity.

Support people and their partners or carers in making treatment decisions, taking into account the effects on quality of life as well as survival.

Offer people with prostate cancer, and their partners or carers, the opportunity to talk to a healthcare professional experienced in dealing with psychosexual issues at any stage of the condition and its treatment.

Quality standards

The following quality statement is relevant to this part of the interactive flowchart.

1. Discussion with a named nurse specialist

3 Diagnosis

Magnetic resonance imaging and biopsy

Do not routinely offer multiparametric MRI to people with prostate cancer who are not going to be able to have radical treatment.

Offer multiparametric MRI as the first-line investigation for people with suspected clinically localised prostate cancer. Report the results using a 5-point Likert scale.

Offer multiparametric MRI-influenced prostate biopsy [See page 11] to people whose Likert score is 3 or more.

Consider omitting a prostate biopsy for people whose multiparametric MRI Likert score is 1 or 2, but only after discussing the risks and benefits with the person and reaching a shared decision (see factors to consider when discussing the options for people whose multiparametric MRI Likert score is 1 or 2 [See page 10]). If a person opts to have a biopsy, offer systematic prostate biopsy [See page 11].

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

Help people decide whether to have an MRI or prostate biopsy by discussing:

- their PSA level
- their DRE findings (including an estimate of prostate size)
- any comorbidities, together with their risk factors (including increasing age and black African-Caribbean family origin)
- any history of a previous negative prostate biopsy.

Do not automatically offer a prostate biopsy on the basis of serum PSA level alone.

Give people and their partners or carers information, support and adequate time to decide whether or not they wish to have an MRI or prostate biopsy. Explain the risks (including the increased chance of having to live with the diagnosis of clinically insignificant prostate cancer) and benefits.

If the clinical suspicion of prostate cancer is high, because of a high PSA value and evidence of bone metastases (identified by a positive isotope bone scan or sclerotic metastases on plain

radiographs), do not offer prostate biopsy for histological confirmation unless this is needed as part of a clinical trial.

Have a core member of the urological cancer MDT review the risk factors of all people who have had a negative first prostate biopsy. Discuss with the person that:

- there is still a risk that prostate cancer is present **and**
- the risk is slightly higher if any of the following risk factors are present:
  - the biopsy showed HGPIN
  - the biopsy showed ASAP
  - abnormal digital rectal examination.

Transperineal template biopsy

Do not offer mapping transperineal template biopsy [See page 11] as part of an initial assessment, unless as part of a clinical trial.

See the NICE guideline to find out why we made this recommendation and how it might affect practice.

NICE has published interventional procedures guidance on transperineal template biopsy and mapping of the prostate with **normal arrangements** for clinical governance, consent and audit.

Although the interventional procedures programme found transperineal template biopsy to be safe and efficacious enough to be used under normal governance arrangements, the NICE guideline recommendation should be followed and the procedure should not be offered unless as part of a clinical trial.

If the MRI or biopsy is negative

For people with a negative biopsy who have an MRI Likert score of 3 or more, discuss the possibility of significant disease in an MDT meeting with a view to repeating the prostate biopsy.

For people who have a raised PSA and MRI Likert score of 1 or 2, and who have not had a prostate biopsy, repeat PSA test at 3 to 6 months and:

- offer prostate biopsy if there is a strong suspicion of prostate cancer (for example, PSA density greater than 0.15 ng/ml/ml or PSA velocity greater than 0.75 ng/ml/year, or strong family history), taking into account their life expectancy and comorbidities
- discharge the person to primary care if the level of suspicion is low; advise PSA follow-up at

- 6 months and then every year, and set a PSA level for primary care at which to re-refer based on PSA density (0.15 ng/ml/ml) or velocity (0.75 ng/ml/year).

For people who have a raised PSA, an MRI Likert score of 1 or 2 (or a contraindication to MRI), and negative biopsy, repeat PSA at 3 to 6 months and:

- offer prostate biopsy if there is a strong suspicion of prostate cancer (for example, PSA density greater than 0.15 ng/ml/ml or PSA velocity greater than 0.75 ng/ml/year, or strong family history), taking into account their life expectancy and comorbidities
- discharge the person to primary care if the level of suspicion is low; advise PSA follow up every 2 years, and set a PSA level for primary care at which to re-refer, based on PSA density (0.15 ng/ml/ml) or velocity (0.75 ng/ml/year).

The PROGENSA PCA3 assay and the Prostate Health Index is not recommended in people having investigations for suspected prostate cancer who have had a negative or inconclusive prostate biopsy.

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

Medtech innovation briefings

NICE has published medtech innovation briefings on:

- Paige Prostate for prostate cancer
- trublood-prostate for triaging and diagnosing people with prostate cancer symptoms.

4 Staging

Offer isotope bone scans when hormonal therapy is being deferred as part of watchful waiting [See page 11] to asymptomatic people who are at high risk of developing bone complications.

Consider CT for people with histologically proven prostate cancer for whom MRI is contraindicated if knowledge of the T or N stage could affect management.

For information on risk stratification for people with localised prostate cancer see risk stratification for localised or locally advanced prostate cancer [See page 8].

See the NICE guideline to find out why we made this recommendation and how they might affect practice.

Do not routinely offer isotope bone scans to people with CPG 1 or 2 localised prostate cancer.

See the NICE guideline to find out why we made this recommendation and how they might affect practice.

5 Risk stratification for localised or locally advanced prostate cancer

Urological cancer MDTs should assign a risk category (see table below) to all people with newly diagnosed localised or locally advanced prostate cancer.

Cambridge Prognostic Group (CPG)	Criteria
1	Gleason score 6 (grade group [See page 11] 1) **and** PSA less than 10 microgram/litre **and** Stages T1-T2
2	Gleason score 3 + 4 = 7 (grade group 2) **or** PSA 10 microgram/litre to 20 microgram/litre **and** Stages T1-T2
3	Gleason score 3 + 4 = 7 (grade group 2) **and** PSA 10 microgram/litre to 20 microgram/litre **and** Stages T1-T2 **or** Gleason 4 + 3 = 7 (grade group 3) **and** Stages T1-T2
4	One of: Gleason score 8 (grade group 4), PSA more than 20 microgram/litre, Stage T3
5	Two or more of: Gleason score 8 (grade group 4), PSA more than 20 microgram/litre, Stage T3 **or** Gleason score 9 to 10 (grade group 5) **or** Stage T4

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

NICE has published a medtech innovation briefing on the Prolaris gene expression assay for

assessing long-term risk of prostate cancer progression.

6 Managing localised or locally advanced prostate cancer

See Prostate cancer / Managing localised or locally advanced prostate cancer

7 Managing metastatic prostate cancer

See Prostate cancer / Managing metastatic prostate cancer

Factors to consider when discussing the options for people whose multiparametric MRI Likert score is 1 or 2

There is more than 1 type of prostate biopsy. The most common approach is TRUS biopsy. The data below comes from the PROMIS and ProtecT studies, which used TRUS. There is no equivalent data for other types of biopsy. The ranges given below reflect different definitions of clinically significant prostate cancer (UCL1 and UCL2; see PROMIS publications).

Advantages of undergoing prostate biopsy

You may have prostate cancer that the MRI scan missed:

- between 11 and 28 out of 100 people with a low-risk MRI actually have clinically significant cancer
- there are many effective treatments for clinically significant cancer, which work best for disease that is caught early; this means that, if you actually do have clinically significant cancer that the MRI missed, you will have a better chance of long-term survival if the biopsy finds it.

Disadvantages of undergoing prostate biopsy

There is no guarantee that a prostate biopsy will find any disease that is there. Prostate biopsies find less than half of the clinically significant prostate cancers that MRI scans miss.

You may be diagnosed with clinically insignificant prostate cancer. This is disease that is unlikely to be life-threatening, but will need monitoring and may lead to treatment. Therefore, if someone has prostate cancer that truly is clinically insignificant, it is better not to find it. Between 18 and 23 out of 100 people with a low-risk MRI get a diagnosis of clinically insignificant prostate cancer if they have a prostate biopsy.

The most common type of biopsy, transrectal ultrasound-guided (TRUS), has some rare but important complications. The most serious is sepsis, which develops in a bit less than 1 out of 100 people. Other serious complications, including acute urinary retention, severe haematuria and severe rectal bleeding may need hospitalisation.

TRUS biopsy has less fewer serious complications that make it unpleasant to undergo for some people.

On average:

- 3 out of 100 people feel light-headed or dizzy immediately after the biopsy
- 44 out of 100 people report pain; in 15 of them, it will last for at least 2 weeks; 7 will consider it a moderate or serious problem
- 20 out of 100 people develop a fever; in 3 of them, it will last for at least 2 weeks; 5 will consider it a moderate or serious problem
- 66 out of 100 people have blood in their urine; in 20 of them, it will last for at least 2 weeks; 6 will consider it a moderate or serious problem
- 37 out of 100 people have blood in their bowel movements; in 5 of them, it will last for at least 2 weeks; 2 will consider it a moderate or serious problem
- 90 out of 100 people have blood in their semen; in 60 of them, it will last for at least 2 weeks; 25 will consider it a moderate or serious problem.

Grade group refers to the 2019 International Society of Urological Pathology grade groupings for prostate cancer.

The information from the mpMRI scan taken before prostate biopsy is used to determine the best needle placement. In rare cases, the biopsy may be MRI-guided (the needle is inserted within the MRI machine). In most cases, the biopsy that follows the mpMRI will be ultrasound-guided, but the specific area(s) targeted will be predetermined by the mpMRI data.

The site for biopsy can be targeted based on multiparametric MRI findings, or systematically but not guided by MRI. Most often there is a combination of both targeted and systematic MRI. The method used for the biopsy can be either transperineal or TRUS.

A template biopsy is normally performed under a general anaesthetic, and involves taking transperineal core biopsies using a grid system. This might involve taking multiple cores from multiple sites, but usually 2 to 3 cores from 8 sites. A mapping template biopsy is where 20 sites are systematically sampled, with 2 or 3 cores per site, sometimes meaning over 50 core biopsies are taken.

This is part of a strategy for 'controlling' rather than 'curing' prostate cancer and is aimed at people with localised prostate cancer who do not ever wish to have curative treatment, or it is not suitable for them. Instead, it involves the deferred use of hormone therapy. Watchful waiting avoids the use of surgery or radiation, but implies that curative treatment will not be attempted.

Glossary

ASAP

atypical small acinar proliferation

CPG

Cambridge Prognostic Group

DRE

digital rectal examination

HGPIN

high-grade prostatic intra-epithelial neoplasia

Localised prostate cancer

(cancer that has been staged as T1 or T2 [confined to the prostate gland])

MDT

multidisciplinary team

MDTs

multidisciplinary teams

Multiparametric MRI

(an MRI study that incorporates anatomical and functional information about the prostate; the minimum functional information includes T2-weighted, diffusion-weighted imaging and dynamic contrast enhanced imaging)

PSA

prostate-specific antigen

Sources

Prostate cancer: diagnosis and management (2019 updated 2021) NICE guideline NG131

Improving supportive and palliative care for adults with cancer (2004) NICE guideline CSG4

Improving outcomes in urological cancers (2002) NICE guideline CSG2

Your responsibility

Guidelines

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Technology appraisals

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health

professionals are expected to take these recommendations fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this interactive flowchart is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the recommendations to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Medical technologies guidance, diagnostics guidance and interventional procedures guidance

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take these recommendations fully into account. However, the interactive flowchart does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the recommendations, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this interactive flowchart should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.